

**EWG M2 Recommendation to the ICH Steering Committee**  
**Electronic Standards for the Transfer of Regulatory Information (ESTRI)**  
**Network - Recommendation 3.1** 30APR1996

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**Title:** Network 3.1 - Messaging

**Date:** 30 April 1996

**Background:**

It is recognized that there exists a need to exchange information in a rapid fashion using messaging over computer networks. The information exchanged may take a variety of forms and content, ranging from simple, informal communication to complex, structured documents.

**Recommendation:**

The Expert Working Group recommends that the following standards for providing the capability for electronic messaging over networks be adopted by the Steering Committee:

- SMTP/MIME as defined by RFC 821, RFC 822, RFC 1521, and RFC 1522
- X.400 (1988) as defined by ISO 10021

**Conditions:**

- Both of these standards are to be implemented and supported by each Regulatory Authority. Once implemented, Industry could select either standard to use when communicating with any Authority.
- The Regulatory Authorities must coordinate their respective implementations of both messaging standards at their ESTRI Gateway to ensure international compatibility. A test must be developed and conducted in order to ensure compatibility and interoperability among Authorities when a new installation is implemented or whenever changes (e.g., new software products) are made to existing installations. This test will also be used to determine that industry sites are compatible with the Regulatory Authority sites.
- Each installation must support the transmission and receipt of files at least 1 MB in size. This size requirement can be expected to increase as networking technology improves.

**Remarks:**

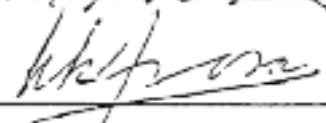

None.

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**SIGNATURES**

Topic Leader:

<p>&lt;EU&gt; <u></u></p> <p>&lt;FDA&gt; <u></u></p> <p>&lt;MHW&gt; <u></u></p>	<p>&lt;EFPIA&gt; <u></u></p> <p>&lt;PhRMA&gt; <u></u></p> <p>&lt;JPMA&gt; <u></u></p>
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Observer:

<HPB> 